

Human Tissue Authority response to the Welsh Government's White Paper: Proposals for Legislation on Organ and Tissue Donation

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1. The Human Tissue Authority (HTA) is committed to working with the Welsh Government on the development of their proposal to introduce an opt-out system in Wales and the subsequent practical implications of such a system.
2. The HTA is a statutory regulator, established by the Human Tissue Act 2004 (the Act). The core principle of the Act is that of consent, and the HTA is responsible for ensuring that consent is in place for a range of activities involving human tissue and cells, including transplantation. The Act applies to England, Wales and Northern Ireland.
3. As the statutory regulator it is not the role of the HTA to take a view on the benefits or detriments of the introduction of an opt-out system in Wales, but rather to provide advice and guidance based on the experience we have gained over the past seven years.
4. The HTA welcomes the opportunity to respond to the Welsh Government's White Paper on the proposals for legislation on organ and tissue donation.
5. The HTA notes the commitment made by the Welsh Government to introduce legislation on an opt-out system for organ donation in their election manifesto.¹
6. The HTA is charged with considering for approval each case of living organ donation in the UK by Regulations² and we note that the Welsh Government

¹ Page 53 – Welsh Labour Manifesto 2011

does not seek to make any changes to the consent provisions of the Act in regard to living organ donation.

7. The HTA is also the Competent Authority designate for the EU Directive on the Quality and Safety of Human Organs Intended for Transplantation³ for the whole of the UK. This Directive will be incorporated into UK law by Statutory Instrument and must become operational on or before 27 August 2012.
8. In our response we have first given an overview and then covered issues of particular interest to the HTA as the body which regulates consent for deceased organ donation in Wales, and finally addressed the specific questions posed by the Welsh Government in their Consultation Document.
9. Please note that when organ donation is referred to in this document, this should be read to include tissue donation.

Overview

10. The Human Tissue Act 2004, associated Regulations and guidance issued by the HTA provide the statutory framework for consent for the removal, storage and use of human tissue and organs. The Act includes a list of “scheduled purposes” for which “appropriate consent” is required, which include transplantation and research. Consent is a central feature of the Act and obtaining appropriate consent was given such prominence by Parliament that it created a criminal offence for failure to do so.
11. The Act defines the person or people from whom consent should be sought, and stipulates that the giving of consent is a positive act.⁴
12. The HTA's Code of Practice on Consent states that:

“For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.”
13. The proposal laid out by the Welsh Government in the White Paper would require changes to primary legislation and, as the body created under the Act to be the guardian of consent, the HTA has significant interest in these

² The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

³ 2010/53/EU

⁴ s.3 HTA 2004

changes. While the technical aspects of amending the legislation will be a matter for the Department of Health, the duty to uphold the consent principles in the Act will remain the responsibility of the HTA, with the sole exception of deceased organ donation for people who both live and die in Wales. The White Paper does not provide sufficient detail on how the proposed changes will impact on the work of the HTA and we would welcome clarity on this as soon as is feasible.

14. The principle enshrined in the existing legislation on organ donation and consent is that the individual has the right to make an autonomous decision in life in regard to their wishes on organ donation. When they have not made any decision in life, the Act provides a hierarchy of family members and friends who will be asked to make the decision on behalf of the potential donor.

15. If our reading of the Welsh Government's proposals is correct, we would suggest that:

- a) everyone affected by the change in the law must be individually and personally informed that they are affected; and
- b) there must be a rolling programme of communication to ensure those who become affected by the change are informed (for example those rising 18 or moving to live in Wales); and
- c) everyone affected must be given the opportunity to opt-out at any time, including information on the mechanism to register their withholding of consent; and
- d) everyone affected must have access to sufficient information to make that decision; and
- e) everyone affected must be given information that if they die in England, Scotland or Northern Ireland the Human Tissue legislation for each country will apply and not the Welsh legislation.

16. The suggestions above are based on our experience in the regulation of "appropriate consent" for the purpose of transplantation since 2005. When complaints have arisen, or mistakes made, the common themes have been a lack of information or the inadequacy of the systems in place.⁵ The Welsh Government has the opportunity to learn from previous errors and create a system which benefits from hindsight, and we would urge that a comprehensive review of the introduction of opt-out systems in other countries is undertaken (including Spain and Brazil which provide quite

⁵ Review of the Organ Donor Register, Sir Gordon Duff, 2010

differing examples), as well as detailed analysis of problems which have occurred in the existing system in the UK.

17. The adoption of the suggestions made above would mean that while there would be dual systems operating in England and Wales, based on a different approach to the decision of the individual in life. We believe that this would require the HTA and Welsh Government to work collaboratively, even though the systems would be different.
18. We note that the Welsh Government is committed to ensuring there is a successful rolling communications campaign. The HTA believes that this will be vital, as while this initiative may be headline news for a short period of time, there will always be a need to ensure all those affected are aware of the options available to them.
19. The proposal presented in the White Paper bears many similarities to a system of mandated choice, in the sense that there is likely to be a register of those that have stated they wish to donate and a register of those that do not wish to donate; those that have not registered a wish either way will be presumed to have consented to donation. We would urge the Welsh Government to consider whether this is truly an opt-out system or whether it is more akin to a mandated choice system, in order to provide clarity to people who live in Wales. There may be benefit in ensuring that the act of an individual adding their details to one of the registers, would mean automatic deregistration from the other.
20. Throughout our response we highlight that certainty and clarity will be two of the key factors in the successful implementation of a new system for organ donation in Wales. We believe that these two factors will facilitate the inclusion of the suggestions above and bring benefits to those living and dying in Wales and the clinical teams involved in organ donation.

Issues of particular interest to the HTA

Research

21. The HTA notes that the White Paper states that the proposals will apply to transplantation only, and not other activities such as research.
22. Consent for research is regularly sought from the family at the same time as consent for organ donation and this is viewed as an effective and efficient way of securing consent to both activities, particularly in the event that material is removed for the purpose of transplantation and is subsequently deemed unsuitable, but can be used for research.

23. Stakeholders working within tissue banks have contacted the HTA to express concern that there may be a reduction in the consents received for research, particularly in cases where the primary intention had been removal for transplantation.
24. We have learnt over the past seven years that the activities of transplantation and research often go hand in hand, and while the intention is that the proposals will only affect transplantation, attention should be given as to how any change may impact on research.
25. The HTA urges the Welsh Government to fully consider how the proposed changes could impact on research and we would welcome the opportunity to discuss this further.

Tissue from the deceased

26. As it is intended that the proposed opt-out system will apply to the donation of tissue such as skin, bone and corneas (as well as solid organs), consideration will need to be given to the impact of this on the work of pathologists and other professionals working in mortuaries, and also on coroners who authorise the vast majority of post mortem examinations.

Measuring the impact of the new system

27. The HTA is keen, as we understand are a range of other bodies within the transplant community, to fully understand how the change to the proposed opt-out system will ultimately affect the rate of deceased organ donation in Wales. We urge the Welsh Government to consider how they will measure the success or otherwise of the move to an opt-out system, and how they can separate the impact of other initiatives from this significant change.
28. The HTA notes that in other countries in which an opt-out system has been introduced, health officials have commented, post-implementation, that it is very difficult to identify the benefit this particular measures has brought,⁶ and we believe the Welsh Government is in a position to learn from the mistakes of the past and plan in good time how they will evaluate this change.

⁶http://www.organdonation.nhs.uk/ukt/newsroom/statements_and_stances/statements/opt_in_or_out.jsp

Consultation Questions

Question One

The White Paper sets out individuals must have lived in Wales for a sufficient period of time before being included in the soft opt-out system.

- ***What factors should be taken into account when determining whether an individual 'lives in Wales'?***
 - ***What should that period of time be?***
29. The particular factors which should be taken into account (for example, length of residency, permanency of residency or the right to vote in Welsh elections) are less important from our perspective than the public being certain as to whether or not they would be classed as living in Wales for the purpose of organ donation.
30. The HTA is not in a position to offer advice on particular factors, but we stress the need for an individual to be able to ascertain quickly and easily whether or not they would be considered to “live” in Wales. This could be through a free phone number, via a website or by a postal campaign, but it should be possible for any individual to access this information at any time, particularly those in the most vulnerable sectors of society.
31. We believe that a failure to offer such a service may lead to confusion and uncertainty which could taint the proposed opt-out system.
32. It is unclear how the Specialist Nurse for Organ Donation (SNOD) or other members of the clinical team involved in organ donation working in a Welsh hospital would ascertain whether a potential donor was classed as living in Wales. They would need to be certain of this at an early stage in the exploration of organ donation to know which system to apply. A failure to establish consent under the Act could lead to a breach of the legislation which could result in a fine or a period of imprisonment, or both for the person who removes the organ.⁷
33. While the HTA is not in a position to offer specific advice on the period of time a person should reside in Wales before being considered to live in Wales for the purpose of organ donation, we would echo the points made in the White Paper that this must be long enough for the person to become aware of the opt-out system and the options available to them. The time

⁷ s.5 HTA 2004

period should be widely communicated, through a range of channels, to ensure a high level of coverage.

Question Two

Do you agree discussions between clinicians and family in the event of an individual's death, will identify and safeguard those who lack capacity?

34. The assessment of whether a deceased person had capacity prior to death, before moving to examine whether a decision to consent or withhold consent to a particular activity was made is an exceptionally complex area to make provision for.
35. It is not clear from either the White Paper or this question whether the intention is to approach every family to establish whether or not the individual had the capacity to withhold consent, or whether this would only occur in cases where there were indicators of a lack of capacity. Such an exploration will potentially bring more stress to the grieving family and it will be important that the clinicians making these approaches have specific training on both how to approach this issue, and the Mental Capacity Act 2005.
36. For those people who had permanently lacked the capacity to make a decision about transplantation during life, a discussion with the family would be a pragmatic way to explore the issue of organ donation. However, some investigation as to whether the family had the right/responsibility to advocate for that person should be explored by the medical team. This may be ascertained through discussions with the team treating the person for the condition/s that caused their lack of capacity, where appropriate.
37. For those people who had temporarily lacked capacity it is much less clear how a discussion with their family would help to ascertain the capacity prior to death in relation to decisions about transplantation, and the if that person did have capacity at the relevant time how to ascertain the deceased person's wishes, unless these are recorded at a time when they did have capacity.
38. We note that the Organ Donor Register (ODR) which currently records the details of those people who wish to donate does not deal with the issue of their capacity to consent, as the Mental Capacity Act makes clear that there is a presumption favour of capacity and that common practice involves a discussion with the family to establish whether there may be any concerns in relation to capacity. However, there is a conceptual difference between the current system which allows a person to actively indicate their consent, and

the proposed system which relies on their omission to register their decision to opt-out. It is likely to be far more difficult to address the public's concerns on decision making when there is a presumption of consent to organ donation.

Question Three

Do you agree that the soft opt-out system for Wales should only apply to persons aged 18 years and over?

39. The HTA is not in a position to advise on the age limits which should be applied in the proposed system although we recognise the practical approach to adopt the age used in Act, which is different from that used in Scotland. However, we are able to give some illustration as to the current situation which may prove useful to the Welsh Government.
40. Under the Act an adult is defined as being a person aged 18 or over.⁸ However, specific provision is made for children under the age of 18 who have made a decision to consent. If someone under the age of 18 or their parent has given appropriate consent to organ donation, then under the Act this consent should stand.
41. Under the Human Tissue (Scotland) Act 2006 an adult is defined as being a person aged 16 or over,⁹ and similar provisions are made to those in the Act for those under this age but over the age of 12 who are able to give consent, defined in Scotland as "authorisation".
42. While there is benefit in the flexible approach afforded by the Act, in practice when the potential donor is under 18 their parent/s will always be consulted to discuss their wishes. As stated above, the HTA believes that certainty and clarity are key in the introduction of a new system and therefore we support a specific age being included in the legislation to provide clarity as to who is considered to be an adult for the purpose of organ donation.

Question Four

Do you agree with the retention of the existing Organ Donor Register to be operated in conjunction with the soft opt-out system?

⁸ s.54 HTA 20047

⁹ Part 5(17)

43. The HTA notes the Welsh Government's commitment to retain the ODR in Wales, and we acknowledge the positive and altruistic feelings many people get from being able to express their wishes positively in life.
44. However, referring once again to the principles of certainty and clarity, the existence of two registers both dealing with the same matter is fraught with difficulties.
45. It would be possible to regularly "cleanse" the data and run each register's information against each other. This would also require each individual to give consent for the sharing of confidential personal information across two registers. However, with people occasionally changing names and regularly changing addresses, this would provide a dramatic increase in workload for those managing the two registers.
46. The White Paper notes that if a person who ordinarily lives in Wales dies in England, Northern Ireland or Scotland, then the ODR will be checked to establish if they had registered to donate. For those people who wish to be donors then the ODR will remain a valuable tool, unless the Welsh Government decides to opt for a system of registration which records both yes and no responses which is accessible by all hospitals in the UK.
47. It would also appear very difficult to prevent a person living in Wales from signing the ODR, and the systems which would need to be put in place to do this would be costly.
48. On balance, it seems that it is unrealistic to make the ODR inaccessible to people who live in Wales. However the issue of contradictory registration systems must be addressed prior to the implementation of any legislation to ensure there is clear guidance on how this should be communicated in order to reduce any further distress to the bereaved.

Question Five

In relation to the record keeping options for the soft opt-out system:

- ***Which of the suggested options do you prefer?***
- ***Are there any other options you feel would provide an effective and secure system?***

49. While the HTA does not have a preference for any of the options listed (we believe, however, that Option D does not go as far as the other options in fulfilling the criteria set by the Welsh Government and this is addressed below), we would again highlight the need for certainty and clarity.

50. The option chosen needs to work for both the person who lives in Wales and the clinician who works in a Welsh hospital. Therefore an individual must be able to make their decision known easily and this decision must be registered quickly, ideally with a check in place (such as the letter NHS Blood and Transplant sends registrants to the ODR to confirm their registration or changes to their registration), and the individual should be able to change their mind and have this recorded quickly and accurately.
51. A SNOD needs to be sure what information they should be sharing with the potential donor's family in relation to their recorded wishes. They need to be able to trust the system so they can communicate clearly with the family and prevent any additional undue upset.
52. Options A, B and C all potentially fulfil the above criteria if the system is well designed and managed. However, the issue of contradictory information being held by the Welsh Government and the ODR exists with all three of these options and a solution to this problem will need to be found before embarking on the design of a new system.
53. None of the options detailed at paragraph 56 allow an individual to establish whether or not this system affects them. However, as noted above, if the response to a binary set of questions gives certainty and clarity to an individual as to whether or not they are classified as living in Wales, and they understand that the country in which they die will be relevant, we believe this would be adequate.
54. The HTA considers Option D to be the least desirable of the four as it compels an individual to have a conversation with someone (their GP in this case) about their wishes on organ donation, and this may not be something they feel comfortable doing. Indeed, for some the thought of having to tell a medical professional they do not wish to be considered as a donor may be embarrassing and uncomfortable, and any aspect of the system which could fetter the individual's ability to say no may be open to legal challenge. The fact that under such a system the individual's wishes would not be held centrally is also of concern as it is logical to conclude that this information may be more difficult for SNODs to access as a matter of urgency.
55. It is also true that a percentage of the population are not registered with a GP, and many of these are in the most vulnerable groups.¹⁰
56. The Welsh Government states in paragraph 6 that those to whom the system applies will have the opportunity to make an objection to donation of their

¹⁰ Page 5 <http://www.revolving-doors.org.uk/documents/liberating-nhs-response/>

organs. The HTA believes that a decision to compel an individual to meet with their GP on this issue does not adequately fulfil this criterion.

57. As the proposal is to retain the ODR in Wales it would seem logical that this mechanism could also be used to register the withholding of consent for those whom the system affects in Wales. As a matter of law, a decision not to consent has force under the Act, there would be real merit to adapting the ODR to allow an individual residing anywhere in the UK to register both a yes and a no. This could be considered as part of the work NHSBT is undertaking to address the recommendations in Sir Gordon Duff's Review of the Organ Donor Register published in autumn 2010.

Question Six

What is the role of the family in safeguarding the wishes of the deceased?

58. There is value in separating the legal and ethical aspects to this question.

59. Under the current legislation, when an individual has consented to transplantation after death, then the family has no further legal responsibility in relation consent. However, operationally it would be impractical not to involve the family or friends. A medical and social history of the donor is taken from their family or friends to allow a full risk assessment to take place as to whether they are a suitable donor. Therefore they are involved at this stage, and, if they felt strongly about donation, could decide to withhold this information no matter what the individual's recorded wishes were.

60. Ethically, it would be most uncomfortable, if not unconscionable, to many involved in organ donation, from the nursing staff to the surgeon, to proceed with retrieval for transplantation against the wishes of the family. Causing additional upset to the family during the period of bereavement implies a harm against the living which in the UK does not fit with our positive approach to donation.

61. Under the opt-out system proposed the family would fulfil a similar role to that at present, that is to say they would be informed of the donor's decision and asked whether the donor had changed their mind. The difference is that the default position in Wales would give rise to them being informed that there is a legal presumption the donor wished to donate and the positive aspect that an ODR registration can bring to that conversation is lost. At the present time SNODs are able to approach the families of those registered on the ODR with the positive message that they are in a position to fulfil their relative's wishes, and consideration should be given as to how this message will be conveyed in an opt-out system.

62. There is also the question of what would happen if a family stated that a recently registered objection to donation was incorrect. Consideration needs to be given as to how the SNOD should be required to investigate this further.
63. The family can only safeguard the donor's wishes if they are aware of them, and, as stated in the White Paper, more work needs to be done to promote discussion within families about organ donation. The Welsh Government goes on to state that the introduction of an opt-out system will lead to this. However, this is not expanded upon, and it will be of interest to the wider transplant community to fully understand the Welsh Government's plans in this area.

Question Seven

How can the Welsh Government ensure that the public awareness campaign is effective?

64. The HTA has not been required to run a public awareness campaign in the past, and can only offer a generalised response to this question.
65. The aim of the public awareness campaign should be to provide information, for that information to be clear and accessible, and to leave the public feeling certain in their understanding of the new system and the implications it has for them.
66. As with any such campaign there will be pockets of the population who are difficult to reach. All efforts should be made to communicate with these groups, and to capitalise on the lessons learnt from previous campaigns. There would be value in the Welsh Government working with other administrations which have introduced such a system to assess which methods were the most successful.
67. Effective monitoring throughout the initial campaign will be important to establish whether any changes need to be made and to gain a sound understanding of the level of penetration. This will help to inform how the ongoing communication campaign/s should be run.
68. It will be important to remember that communication will be needed with residents in the other home nations, particularly those living in the counties bordering Wales who may be taken to a Welsh hospital in the event of illness, to make clear the system will not apply to them, even if they die in a Welsh hospital.

69. The HTA is aware that we may need to run a communication campaign with professionals to signpost where and when the Act applies and when the new Welsh legislation applies. Consideration will be given to this as and when we have further information on the Welsh Government's communications plan.

Question Eight

The Welsh Government would welcome your views on the potential impact of the proposed soft-opt out system for the Welsh Language, race, faith, disability, age, sexual orientation, gender, gender reassignment, marriage or civil partnership.

70. The HTA notes the Impact Assessment included in the White Paper.

71. We are not in a position to add significantly to the information provided, but would recommend that some exploration of the comparatively high rates of living organ donation amongst BME communities takes place to establish whether this has any learning for deceased donation.